Complete Summary

GUIDELINE TITLE

Immunizations.

BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Immunizations. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2008 Oct. 64 p. [67 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version:

Institute for Clinical Systems Improvement (ICSI). Immunization update. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2007 Dec. 4 p.

Institute for Clinical Systems Improvement (ICSI). Immunizations. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2007 Oct. 67 p. [77 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

- Diphtheria
- Tetanus

- Pertussis
- Poliomyelitis
- Measles
- Mumps
- Rubella
- Pneumococcal disease
- Varicella
- *Haemophilus influenza b* (Hib) infection
- Hepatitis B (Hep B)
- Influenza
- Hepatitis A (Hep A)
- Meningococcal infection
- Rotavirus infection
- Human papilloma virus (HPV) infection
- Herpes zoster/shingles

GUIDELINE CATEGORY

Prevention

CLINICAL SPECIALTY

Family Practice
Geriatrics
Infectious Diseases
Internal Medicine
Pediatrics
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Health Plans
Hospitals
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To increase the percentage of patients who are on time with recommended immunizations
- To increase the percentage of patients/parents who receive education regarding immunization
- To reduce missed opportunities for administering immunizations
- To increase the percentage of patients who are not on time with recommended immunizations who have a catch-up plan

TARGET POPULATION

Persons of all ages in the United States seeking immunity from infectious diseases through the use of vaccines

INTERVENTIONS AND PRACTICES CONSIDERED

1. Routine immunization for infants and children, including:
    - Diphtheria and tetanus toxoids with acellular pertussis (DTaP); tetanus-diphtheria-acellular pertussis vaccine (Tdap)
    - Inactivated poliovirus vaccine (IPV)
    - Measles, mumps, rubella (MMR) or combined measles, mumps, rubella and varicella vaccine (MMRV)
    - Varicella vaccine
    - Pneumococcal 7 valent conjugated polysaccharide vaccine (PCV7)
    - *Haemophilus influenzae b* (Hib) conjugate vaccine
    - Rotavirus vaccine
    - Hepatitis B (Hep B) vaccine
    - Hepatitis A (Hep A) vaccine
    - Meningococcal conjugate vaccine; meningococcal unconjugated polysaccharide vaccine
    - Influenza vaccine (inactivated, injectable influenza vaccine and live, attenuated influenza vaccine)
    - Human papilloma virus (HPV) vaccine

2. Adult immunization, including:
    - Tetanus, diphtheria (Td); Tdap
    - IPV
    - MMR vaccine
    - Varicella vaccine
    - Influenza vaccine
    - Pneumococcal (PPV23) vaccine
    - Hep A vaccine
    - Hep B vaccine
    - Meningococcal vaccine
    - HPV vaccine
    - Herpes zoster/shingles vaccine

3. Patient/parent education
4. Recording of adverse events
5. Development of systems to track the immunization status of patients

MAJOR OUTCOMES CONSIDERED

- Antibody responses
- Incidence of disease or illness
- Risk of hospitalization and death
- Safety and protective efficacy of vaccinations
- Cost-effectiveness of vaccinations
- Adverse effects of vaccinations

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

A literature search of clinical trials, meta-analysis, and systematic reviews is performed.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Conclusion Grades:

Key conclusions (as determined by the work group) are supported by a conclusion grading worksheet that summarizes the important studies pertaining to the conclusion. Individual studies are classed according to the system presented below, and are designated as positive, negative, or neutral to reflect the study quality. Conclusion grades are determined by the work group based on the following definitions:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results of different studies or because of serious doubts about generalizability, bias, research design flaws, or

adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

Grade Not Assignable: There is no evidence available that directly supports or refutes the conclusion.

Study Quality Designations:

The quality of the primary research reports and systematic reviews are designated in the following ways on the conclusion grading worksheets:

Positive: indicates that the report or review has clearly addressed issues of inclusion/exclusion, bias, generalizability, and data collection and analysis.

Negative: indicates that these issues (inclusion/exclusion, bias, generalizability, and data collection and analysis) have not been adequately addressed.

Neutral: indicates that the report or review is neither exceptionally strong nor exceptionally weak.

Not Applicable: indicates that the report is not a primary reference or a systematic review and therefore the quality has not been assessed.

Classes of Research Reports:

A. Primary Reports of New Data Collection:

Class A:

- Randomized, controlled trial

Class B:

- Cohort study

Class C:

- Non-randomized trial with concurrent or historical controls
- Case-control study
- Study of sensitivity and specificity of a diagnostic test
- Population-based descriptive study

Class D:

- Cross-sectional study
- Case series
- Case report

B. Reports that Synthesize or Reflect upon Collections of Primary Reports:

Class M:

- Meta-analysis
- Systematic review
- Decision analysis
- Cost-effectiveness analysis

Class R:

- Consensus statement
- Consensus report
- Narrative review

Class X:

- Medical opinion

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Guideline Development Process

Each guideline, order set, and protocol is developed by a 6- to 12-member work group that includes physicians, nurses, pharmacists, other healthcare professionals relevant to the topic, along with an Institute for Clinical Systems Improvement (ICSI) staff facilitator. Ordinarily, one of the physicians will be the leader. Most work group members are recruited from ICSI member organizations, but if there is expertise not represented by ICSI members, 1 or 2 members may be recruited from medical groups or hospitals outside of ICSI.

The work group meets for seven to eight three-hour meetings to develop the guideline. A literature search and review is performed and the work group members, under the coordination of the ICSI staff facilitator, develop the algorithm and write the annotations and footnotes and literature citations.

Once the final draft copy of the guideline is developed, the guideline goes to the ICSI members for critical review.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Cost-Effectiveness of Varicella Vaccine

It is cost effective to do immune status testing for all persons 13 years old of age and older, who believe they are nonimmune, before vaccinating. More than 75% of them will be immune. The prevaccination testing will also substantially reduce the average number of needle sticks that patients in this age range need. For most that number will be only one.

Cost-Effectiveness of Tetanus-Diphtheria Booster

A schedule of a single tetanus-diphtheria (Td) booster or diphtheria, tetanus, acellular pertussis (DTaP) dose between 50 and 65 years has recently been considered cost effective, but evidence about the adequacy of protection against diphtheria with this approach is currently lacking.

Cost-Effectiveness of Meningococcal Vaccination (MCV-4)

The cost effectiveness of MCV-4 was studied in a hypothetical population over a defined time frame. It was concluded that vaccination would reduce the burden of disease, but at a relatively high net societal cost.

Cost-Effectiveness Human Papillomavirus (HPV) Vaccine

In economic models, the most cost-effective schedule is to routinely immunize all women at ages 11-12 and to do catch-up through age 26. It is not necessary or desirable to test for previous HPV infection when starting the immunization series for sexually active women.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Critical Review Process

Every newly developed guideline or a guideline with significant change is sent to Institute for Clinical Systems Improvement (ICSI) members for Critical Review. The purpose of critical review is to provide an opportunity for the clinicians in the member groups to review the science behind the recommendations and focus on the content of the guideline. Critical review also provides an opportunity for clinicians in each group to come to consensus on feedback they wish to give the work group and to consider changes necessary across systems in their organization to implement the guideline.

All member organizations are expected to respond to critical review guidelines. Critical review of guidelines is a criterion for continued membership within ICSI.

After the critical review period, the guideline work group reconvenes to review the comments and make changes, as appropriate. The work group prepares a written response to all comments.

Approval

Each guideline, order set, and protocol is approved by the appropriate steering committee. There is one steering committee each for Respiratory, Cardiovascular, Women's Health, and Preventive Services. The Committee for Evidence-based Practice approves guidelines, order sets, and protocols not associated with a particular category. The steering committees review and approve each guideline based on the following:

- Member comments have been addressed reasonably.
- There is consensus among all ICSI member organizations on the content of the document.
- To the extent of the knowledge of the reviewer, the scientific recommendations within the document are current.
- Either a critical review has been carried out, or to the extent of the knowledge of the reviewer, the changes proposed are sufficiently familiar and sufficiently agreed upon by the users that a new round of critical review is not needed.

Once the guideline, order set, or protocol has been approved, it is posted on the ICSI Web site and released to members for use. Guidelines, order sets, and protocols are reviewed regularly and revised, if warranted.

Revision Process of Existing Guidelines

ICSI scientific documents are revised every 12 to 36 months as indicated by changes in clinical practice and literature. Every 6 months, ICSI checks with the work group to determine if there have been changes in the literature significant enough to cause the document to be revised earlier than scheduled.

Prior to the work group convening to revise the document, ICSI members are asked to review the document and submit comments. During revision, a literature search of clinical trials, meta-analysis, and systematic reviews is performed and reviewed by the work group. The work group meets for 1-2 three-hour meetings to review the literature, respond to member organization comments, and revise the document as appropriate.

If there are changes or additions to the document that would be unfamiliar or unacceptable to member organizations, it is sent to members to review prior to going to the appropriate steering committee for approval.

Review and Comment Process

ICSI members are asked to review and submit comments for every guideline, order set, and protocol prior to the work group convening to revise the document.

The purpose of the Review and Comment process is to provide an opportunity for the clinicians in the member groups to review the science behind the recommendations and focus on the content of the order set and protocol. Review and Comment also provides an opportunity for clinicians in each group to come to consensus on feedback they wish to give the work group and to consider changes needed across systems in their organization to implement the guideline.

All member organizations are encouraged to provide feedback on order sets and protocol; however, responding to Review and Comment is not a criterion for continued membership within ICSI.

After the Review and Comment period, the work group reconvenes to review the comments and make changes as appropriate. The work group prepares a written response to all comments.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Notes from the National Guideline Clearinghouse (NGC) and the Institute for Clinical Systems Improvement (ICSI):

- For a description of what has changed since the previous version of this guidance, refer to Summary of Changes Report -- October 2008.
- The recommendations for immunizations are presented in the form of immunization schedules and an algorithm with a total of 30 components accompanied by detailed annotations. Clinical highlights and immunization schedules are provided below for: *Immunization Schedule for Infants, Children, and Adolescents – Routine and High Risk* and *Immunization Schedule for Adult – Routine and High Risk*. An algorithm for *In-Clinic Immunization* is provided in the original guideline document.
- Vaccine shortages continue to occur in the United States and are the result of a number of factors including companies leaving the vaccine market, manufacturing or production problems, unexpected demand for new vaccines or to changes in vaccine recommendations. On occasion, shortages necessitate temporary changes in recommendations for their use. Information about the shortages including projected duration and recommendations for temporary changes in the immunization schedule are provided by the Advisory Committee on Immunization Practices. The work group recommends that all practitioners be kept abreast of the latest national information on vaccine shortage available at the Centers for Disease Control and Prevention Web site at http://www.cdc.gov/vaccines/news/default.htm.
- Vaccines administered outside the United States can generally be accepted as valid if the schedule was similar to that recommended in the United States (i.e., minimum ages and intervals). Only written documentation should be accepted as evidence of previous vaccination. Written records are more likely to predict protection if the vaccines, dates of administration, intervals between doses, and the person's age at the time of vaccination are comparable to United States recommendations. If a question exists about whether vaccines administered outside the United States were immunogenic, repeating the vaccinations is usually safe and avoids the need to obtain and

interpret serologic tests. If avoiding unnecessary injections is desired, serologic testing might be helpful in determining which vaccinations are needed.

Clinical Highlights

- Utilize all clinical encounters as opportunities to assess a patient's immunization status. (*Annotations #15, 16, 17; Aim #1 - see the original guideline document*)
- Administer at each clinical encounter all immunizations that are due or overdue unless true contraindications exist. (*Annotations #20, 22, 23, 26; Aim #2 - see the original guideline document*)
- Educate patients (parents, if applicable) regarding the importance of infant, childhood, adolescent, and adult immunizations, the recommended schedule and the need to maintain a personal record of immunizations and childhood diseases. (*Annotation #28 - see the original guideline document*)
- Document reasons for not administering immunizations that are clinically indicated, and flag the record for a recall appointment. (*Annotations #23, 24 - see the original guideline document*)
- Document the future plan for administering immunizations. (*Annotation #15, 26, 28; Aim #3 - see the original guideline document*)

***Immunization Schedule for Infants, Children, and Adolescents – Routine and High Risk**

<table>
<tr><th>Vaccine</th><th>Birth</th><th>1 mo</th><th>2 mos</th><th>4 mos</th><th>6 mos</th><th>12 mos</th><th>15 mos</th><th>18 mos</th><th>24 mos</th><th>4-6 yrs</th><th>11-12 yrs</th><th>15-18 yrs</th></tr>
<tr><td>DTaP</td><td></td><td></td><td>X</td><td>X</td><td>X</td><td colspan="3">X</td><td></td><td>X</td><td>Tdap</td><td></td></tr>
<tr><td>IPV</td><td></td><td></td><td>X</td><td>X</td><td colspan="4">X</td><td></td><td>X</td><td></td><td></td></tr>
<tr><td>MMR (MMRV)</td><td colspan="5" rowspan="2">See Annotation #3 in the original guideline document for information on combined measles, mumps, rubella and varicella vaccine (MMRV).</td><td colspan="2">X</td><td></td><td></td><td>X</td><td></td><td></td></tr>
<tr><td>Varicella</td><td colspan="2">X</td><td></td><td></td><td>X</td><td></td><td>X
Verify second dose completed</td></tr>
<tr><td>Pneumococcal (PCV7)</td><td></td><td></td><td>X</td><td>X</td><td>X</td><td colspan="2">X</td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Hib</td><td></td><td></td><td>X</td><td>X</td><td>X</td><td colspan="2">X</td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Rotavirus</td><td></td><td></td><td>X</td><td>X</td><td>X</td><td colspan="2"></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Hep B Schedule 1</td><td>X</td><td colspan="2">X</td><td></td><td colspan="3">X</td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Hep B Schedule 2</td><td></td><td colspan="2">X</td><td>X</td><td colspan="4">X</td><td></td><td></td><td></td><td></td></tr>
<tr><td>Influenza</td><td></td><td colspan="3"></td><td colspan="8">X
annually</td></tr>
</table>

Vaccine	Birth	1 mo	2 mos	4 mos	6 mos	12 mos	15 mos	18 mos	24 mos	4-6 yrs	11-12 yrs	15-18 yrs
Hep A						X 2 doses minimum 6 months interval						
Meningococcal											X	X if previously not received
Human Papilloma Virus (HPV) (females)											X (3-dose series)	X (Catch up if appropriate, 3-dose series)

Abbreviations: DTaP, diphtheria, tetanus, acellular pertussis; Hep A, hepatitis A; Hep B, hepatitis B; Hib, *Haemophilus influenzae* type b; IPV, inactivated poliovirus vaccine; MMR, measles, mumps, and rubella; MMRV, measles, mumps, rubella, varicella; Tdap, tetanus-diphtheria-acellular pertussis

*Please check manufacturer specifications for dosing, as all time intervals may not be needed.

For additional information on immunizing high-risk patients, see Annotation #14 in the original guideline document.

***Immunization Schedule for Adults -- Routine and High-Risk**

Vaccine	19-26 Years	27-39 Years	40-64 Years	65 Years and Older
Td/Tdap	Tdap if previously not immunized, 1 dose Td booster every 10 years, substitute one dose of Tdap for Td			Td booster
IPV	Immunize if not previously immunized			
MMR	Persons born during or after 1957 should have 1-dose measles; a second dose may be required in special circumstances (see Annotation #3 in the original guideline document).			
Varicella	X Verify second dose completed	For all adults who do not have evidence of immunity to varicella, give two doses of varicella vaccine with at least 28 days between the first and second doses. (See Annotation #4 in the original guideline document.)		
Pneumococcal (PPV23)	Immunize high risk groups once. Re-immunize those at risk of			Immunize at 65 if not done previously. Re-immunize

Vaccine	19-26 Years	27-39 Years	40-64 Years	65 Years and Older
	losing immunity once after 5 years.			once if 1st received >5 years ago and before age 65 or an appropriate immunocompromising condition is present.
Hep B	Universal immunization		Immunize those at high risk.	
Influenza	Annually during flu season for individuals age 50 and older, those at high risk, and others.			
Hep A	Immunize those in risk groups			
Meningococcal	X	Immunize those in risk groups		
Human Papilloma Virus (HPV) (females)	X Catch up, if appropriate			
Herpes Zoster/Shingles				Immunize at age 60 and older

Abbreviations: Hep A, hepatitis A; Hep B, hepatitis B; IPV, inactivated polio vaccine; MMR, measles, mumps, rubella; Td, tetanus, diphtheria; Tdap, tetanus-diphtheria-acellular pertussis

*Please check manufacturer specifications for dosing, as all time intervals may not be needed.

For additional information on immunizing high-risk patients, see Annotation #14 in the original guideline document.

The Centers for Disease Control and Prevention (CDC) updates immunizations recommendations in January, July, and October -- please refer to the CDC website http://www.cdc.gov/vaccines for the most current schedule.

CLINICAL ALGORITHM(S)

A detailed and annotated clinical algorithm titled "In-Clinic Immunization Algorithm" is provided in the original guideline document.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Increased percentage of patients on time with recommended immunizations

- Increased percentage of patients/parents who receive education regarding immunizations
- Reduced missed opportunities for administering immunizations
- Increased percentage of patients who are not on time with recommended immunizations who have a catch-up plan

POTENTIAL HARMS

- Adverse effects (i.e., local reactions, fever, mild forms of disease with attenuated formulations) specific to vaccines
- Caution should be exercised if Zostavax is administered to a nursing woman; pregnancy should be avoided for 3 months following vaccination with Zostavax
- A total of 15 confirmed cases of Guillain-Barré Syndrome (GBS) among individuals 11 to 19 years of age occurring within six weeks of vaccination with Menactra have been reported to the Vaccine Adverse Events Reporting System (VAERS). Two additional cases have been confirmed in persons 20 years of age and older. All individuals are reported to be recovering or have recovered. While the number of cases reported is at the edge of statistical significance and suggests a small increased risk of GBS following immunization with Menactra, the limitations in VAERS, and the uncertainty regarding background incidence rates for GBS require that these findings be viewed with caution.
- Postlicensure studies of measles, mumps, rubella, and varicella (MMRV) suggest an increased risk of febrile convulsions 7 to 10 days postvaccination in children aged 12 to 23 months who received MMRV vaccine compared to children who received MMR and varicella separately at the same time. It is estimated that one additional febrile convulsion would occur in every 2,000 children vaccinated with MMRV compared to children who received MMR and varicella concurrently and in separate injections.

CONTRAINDICATIONS

CONTRAINDICATIONS

- Pregnancy is an absolute contraindication to varicella vaccination.
- Live bacterial (Bacillus Calmette-Guérin [BCG], oral typhoid) and viral (CAIV-T, measles, mumps, rubella [MMR], yellow fever, varicella) vaccines are contraindicated in patients with immunodeficiencies. Live, attenuated vaccines contraindicated in human immunodeficiency virus (HIV) positive patients include live, attenuated influenza, herpes zoster vaccine, yellow fever, oral typhoid, BCG and oral polio (not available in the U.S.).
- Normal siblings of immunocompromised children should not receive live oral polio vaccine.

Zostavax® should not be administered to:

- Persons with a history of anaphylactic/anaphylactoid reaction to gelatin or neomycin
- Persons with leukemia, lymphomas or other malignant neoplasms affecting the bone marrow or lymphatic system (however, patients whose leukemia is

in remission and who have not received chemotherapy [e.g., alkylating drugs or anti-metabolites] or radiation for at least three months can receive zoster vaccine); persons with acquired immunodeficiency syndrome (AIDS) or other clinical manifestations of infection with human immunodeficiency viruses including persons with CD4+ T-lymphocyte values less than 200 per mm^3 or less than 15% of total lymphocytes
- Persons with clinical or laboratory evidence of other unspecified cellular immunodeficiency (however, persons with impaired humoral immunity [e.g., hypogammaglobulinemia or dysgammaglobulinemia] can receive zoster vaccine)
- Persons undergoing hematopoietic stem cell transplantation (HSCT)
    - Physicians should assess the immune status of the recipient on a case-by-case basis to determine the relevant risks
    - If a decision is made to vaccinate with zoster vaccine, the vaccine should be administered at least 24 months after transplantation
- Persons receiving immunosuppressant medications including:
    - Greater than 20 mg/day of prednisone or equivalent for more than two weeks
    - Greater than 0.4 mg/kg/day of methotrexate
    - Greater than 3 mg/kg/day of azathioprine
    - Greater than 1.5 mg/kg/day of 6-mercaptopurine
    - Chemotherapy or radiation
    - Tumor necrosis factor inhibitors
    - Other immune modulators
- Persons with active untreated tuberculosis
- Persons who are or may be pregnant
- Zostavax should not be used in children

Persons should not receive live, attenuated influenza vaccine if they:

- Have chronic heart disease
- Have chronic lung disease (including asthma and reactive airway disease)
- Have diabetes
- Have kidney failure
- Have illnesses that weaken the immune system
- Are taking medications that weaken the immune system
- Are children or adolescents receiving aspirin therapy
- Have a history of Guillain-Barré syndrome
- Are pregnant or lactating
- Have a history of allergy to eggs (or any vaccine component)

Live, attenuated influenza vaccine should not be administered within 48 hours after cessation of influenza antiviral therapy, and influenza antiviral medications should not be administered for two weeks after receipt of live, attenuated influenza vaccine.

Use of certain immunosuppressant medications may be a contraindication to administration of certain vaccines, particularly live viral vaccines. As a general rule, avoid administering live viral vaccines (rotavirus, MMR, varicella, zoster, yellow fever) to persons receiving the following medications:

- Corticosteroids

    - Children greater than 2 mg/kg/day or 20 mg/day prednisone or equivalent for greater than two weeks
    - Adults 20 mg/day prednisone or equivalent for greater than two weeks
- Chemotherapy or radiation
- Methotrexate
    - Greater than 0.4 mg/kg/day
- Azathioprine
    - Greater than 3 mg/kg/day
- 6-Mercaptopurine
    - Greater than 1.5 mg/kd/day
- Tumor necrosis factor inhibitors (adalimumab, etanercept, infliximab, etc.)
- Other immune modulators

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- These clinical guidelines are designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and are not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition. A guideline will rarely establish the only approach to a problem.
- This medical guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. Patients are urged to consult a health care professional regarding their own situation and any specific medical questions they may have.
- The Immunization work group realizes that the Centers for Disease Control and Prevention (CDC) update immunization recommendations in January, July and October. The CDC's Web site http://www.cdc.gov/vaccines/ provides the most current schedule.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Once a guideline is approved for general implementation, a medical group can choose to concentrate on the implementation of that guideline. When four or more groups choose the same guideline to implement and they wish to collaborate with others, they may form an action group.

In the action group, each medical group sets specific goals they plan to achieve in improving patient care based on the particular guideline(s). Each medical group shares its experiences and supporting measurement results within the action group. This sharing facilitates a collaborative learning environment. Action group learnings are also documented and shared with interested medical groups within the collaborative.

Currently, action groups may focus on one guideline or a set of guidelines such as hypertension, lipid treatment, and tobacco cessation.

Detailed measurement strategies are presented in the original guideline document to help close the gap between clinical practice and the guideline recommendations. Summaries of the measures are provided in the National Quality Measures Clearinghouse (NQMC).

Key Implementation Recommendations

The following system changes were identified by the guideline work group as key strategies for health care systems to incorporate in support of the implementation of this guideline.

1. Develop tracking systems in order to establish immunization status of patients under the provider's care, with the capability to produce reminders and recalls for immunizations that are due and/or not on time. (*Annotations #15, 17, 29 - see the original guideline document*)
    - Develop a plan for periodic medical record audits, paper medical record or electronic health records in order to track outcomes and identify barriers.

2. Remove barriers to immunization services. (*Annotations #15, 17, 21 - see the original guideline document*)
3. Develop system-based routine standing orders, to include specific criteria around immunizations that may be due at the current visit, or those immunizations not on time, including a statement indicating immunization(s) may be given at any time during the visit (based on specific criteria).
    - Provide staff training and education around routine standing orders.
    - Make it clear to staff that routine standing orders are physician orders that allow for administration of immunizations (those due or not on time).
    - Clearly define those staff who may administer these immunizations (RN, LPN, CMA, etc.).

4. Develop education for providers and staff around patients at risk/high risk who require adjustments or have contradictions to specific (required) immunizations.
    - Develop criteria and alerts for tracking these patients.
    - Develop criteria in paper medical record or electronic health records for documentation of patients at risk/high risk.

5. Develop a means for communicating vaccine shortages to practitioners, as well as providing updates on status of shortages. This information is available on the Centers for Disease Control and Prevention Web site.
6. Patient Safety: Provide education to physicians and staff around risk factors and immunizations in all age groups. Stress the importance of reviewing this guideline and/or any of the resources listed (in this guideline) as a reference.
7. Develop tracking systems to produce periodic immunization audits for use in developing solutions to identified problems. (*Annotation #29- see the original guideline document*)

IMPLEMENTATION TOOLS

Clinical Algorithm
Pocket Guide/Reference Cards
Quality Measures

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

RELATED NQMC MEASURES

- Immunizations: percentage of two-year-old patients who are on time with their primary series of immunizations (DTaP, IPV, MMR/MMRV, PCV7/PPV23, VZV, Hib, Hep B, Hep A, Rota, Influenza).
- Immunizations: percentage of adolescents who are on time with recommended immunizations (Hep B, Hep A, HPV, MMR, MCV4, Tdap, VZV).

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Immunizations. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2008 Oct. 64 p. [67 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2007 Oct (revised 2008 Oct)

GUIDELINE DEVELOPER(S)

Institute for Clinical Systems Improvement - Private Nonprofit Organization

GUIDELINE DEVELOPER COMMENT

Organizations participating in the Institute for Clinical Systems Improvement (ICSI): Affiliated Community Medical Centers, Allina Medical Clinic, Altru Health System, Aspen Medical Group, Avera Health, CentraCare, Columbia Park Medical Group, Community-University Health Care Center, Dakota Clinic, ENT Specialty Care, Fairview Health Services, Family HealthServices Minnesota, Family Practice Medical Center, Gateway Family Health Clinic, Gillette Children's Specialty Healthcare, Grand Itasca Clinic and Hospital, HealthEast Care System, HealthPartners Central Minnesota Clinics, HealthPartners Medical Group and Clinics, Hutchinson Area Health Care, Hutchinson Medical Center, Lakeview Clinic, Mayo Clinic, Mercy Hospital and Health Care Center, MeritCare, Mille Lacs Health System, Minnesota Gastroenterology, Montevideo Clinic, North Clinic, North Memorial Care System, North Suburban Family Physicians, Northwest Family Physicians, Olmsted Medical Center, Park Nicollet Health Services, Pilot City Health Center, Quello Clinic, Ridgeview Medical Center, River Falls Medical Clinic, Saint Mary's/Duluth Clinic Health System, St. Paul Heart Clinic, Sioux Valley Hospitals and Health System, Southside Community Health Services, Stillwater Medical Group, SuperiorHealth Medical Group, University of Minnesota Physicians, Winona Clinic, Ltd., Winona Health

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SOURCE(S) OF FUNDING

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GUIDELINE COMMITTEE

Preventive Services Steering Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Work Group Members: James Nordin, MD (*Work Group Leader*) (HealthPartners Medical Group) (Pediatrics); Emma Carlin, MD (Park Nicollet Health Services) (Family Medicine); Barbara Yawn, MD (Olmsted Medical Center) (Family Medicine); Abinash Virk, MD (Mayo Clinic) (Infectious Disease); Barb Ottis, RN (Park Nicollet Health Services) (Nursing); Renner Anderson, MD (Park Nicollet Health Services) (Pediatrics); Robert Jacobson, MD (Mayo Clinic) (Pediatrics); Sarah Rall, PharmD (Marshfield Clinic) (Pharmacy); Penny Fredrickson (Institute for Clinical Systems Improvement) (Measurement/Implementation Advisor); Melissa Marshall, MBA (Institute for Clinical Systems Improvement) (Facilitator)

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

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documents (guidelines, order sets and protocols). This applies to all work groups (guidelines, order sets and protocols) and committees (Committee on Evidence-Based Practice, Cardiovascular Steering Committee, Women's Health Steering Committee, Preventive & Health Maintenance Steering Committee and Respiratory Steering Committee).

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Dr. Robert Jacobson serves on the data safety monitoring board for Kaiser Permanente of Southern California overseeing a Gardasil trial. He receives less than $10,000 for this commitment.

Barbara Ottis, RN holds stock in Merck and Baxter. She also received speaker fees from GSK in an amount less than $10,000.

Dr. Barbara Yawn negotiated research funds on behalf of Olmsted Medical Center from Merck. Dr. Yawn receives less than $10,000 from Merck for serving on the advisory board for Zostavax.

No other work group members have potential conflicts of interest to disclose.

ICSI's conflict of interest policy and procedures are available for review on ICSI's website at www.icsi.org.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version:

Institute for Clinical Systems Improvement (ICSI). Immunization update. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2007 Dec. 4 p.

Institute for Clinical Systems Improvement (ICSI). Immunizations. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2007 Oct. 67 p. [77 references]

GUIDELINE AVAILABILITY

Electronic copies: Available from the Institute for Clinical Systems Improvement (ICSI) Web site.

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org; e-mail: icsi.info@icsi.org.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Immunizations. Executive summary. Bloomington (MN): Institute for Clinical Systems Improvement, 2008 Oct. 1 p. Electronic copies: Available from the Institute for Clinical Systems Improvement (ICSI) Web site.
- ICSI pocket guidelines. May 2007 edition. Bloomington (MN): Institute for Clinical Systems Improvement, 2007.

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org; e-mail: icsi.info@icsi.org.

PATIENT RESOURCES

None available

NGC STATUS

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